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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHIESI USA INC. and CHIESI FARMACEUTICI S.P.A. Plaintiffs, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LTD., MSN LIFE SCIENCES PRIVATE LIMITED, and ENDO PROCUREMENT OPERATIONS LIMITED Defendants.	C.A. No. _____ *Document Filed Electronically*

COMPLAINT

Plaintiffs Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. (collectively, "Chiesi" or "Plaintiffs") by its undersigned attorneys, for its Complaint against Defendants MSN

Pharmaceuticals Inc. ("MSN Pharmaceuticals"), MSN Laboratories Private Ltd. ("MSN Pvt."), MSN Life Sciences Private Limited ("MSN Life Sciences") (collectively, "MSN"), and Endo Procurement Operations Limited ("Endo") (collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 8,680,052 ("the '052 patent") (attached as Exhibit A hereto), U.S. Patent No. 9,295,687 ("the '687 patent") (attached as Exhibit B hereto), U.S. Patent No. 9,427,448 ("the '448 patent") (attached as Exhibit C hereto), U.S. Patent No. 9,439,921 ("the '921 patent") (attached as Exhibit D hereto), U.S. Patent No. 9,700,575 ("the '575 patent") (attached as Exhibit E hereto), U.S. Patent No. 9,925,265 ("the '265 patent") (attached as Exhibit F hereto), and U.S. Patent No. 10,039,780 ("the '780 patent") (attached as Exhibit G hereto) (collectively, the "patents in suit").

THE PARTIES

2. Chiesi USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

3. Chiesi USA Inc. is the owner of New Drug Application (NDA) No. 204958, which was approved by the U.S. Food and Drug Administration (FDA) for the manufacture and sale of Kengreal® (cangrelor) for injection.

4. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having a principal place of business at Via Palermo, 26 A, 43122 Parma, Italy.

5. Chiesi Farmaceutici S.p.A. is the current owner and assignee of each of the eight (8) patents listed in FDA's publication titled "Approved Drug Products with Therapeutic

Equivalence Evaluations" (commonly known as the "Orange Book") as covering Chiesi's Kengreal®, of which seven (7) are the patents in suit. The seven (7) patents in suit were previously owned by The Medicines Company, on assignment from the inventors, who were employees of The Medicines Company. Upon information and belief, The Medicines Company is a corporation having its principal place of business in Parsippany, New Jersey. Upon information and belief, one or more of the inventors of the patents in suit are located in Parsippany, New Jersey.

6. Upon information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Upon information and belief, MSN Pharmaceuticals is a wholly owned subsidiary of MSN Pvt. MSN Pvt.'s website states that MSN Pharmaceuticals "is a fully owned subsidiary of the MSN group of companies and is specialized in contract development and manufacturing of high-quality generic pharmaceutical products."[1]

7. Upon information and belief, MSN Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Service to do business in New Jersey under entity ID No. 0400627791.

8. Upon information and belief, MSN Pharmaceuticals is in the business of, among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey. MSN Pvt.'s website states that MSN Pharmaceuticals Inc. "is a state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey."[2] MSN Pvt.'s website

[1] http://www.msnlabs.com/msnpi.html (last visited Sept. 30, 2019).
[2] http://www.msnlabs.com/msnpi.html (last visited Sept. 30, 2019).

further states that "the facility is replete with Corporate Offices, Research and Development area, Laboratories, and Manufacturing Units."[3]

9. Upon information and belief, Defendant MSN Pvt. is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana 500018, India.

10. Upon information and belief, MSN Pharmaceuticals is an authorized U.S. Agent for MSN Pvt. Upon information and belief, MSN Pharmaceuticals acts at the direction, and for the benefit, of MSN Pvt., and is controlled and/or dominated by MSN Pvt.

11. Upon information and belief, MSN Pharmaceuticals is an authorized U.S. Agent for MSN Pvt. with respect to Abbreviated New Drug Applications ("ANDAs") submitted to the FDA pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), including at least ANDA No. 208457 (Linagliptin Tablets, 5 mg) and ANDA No. 208256 (Roflumilast Tablets, 500 mcg).

12. Upon information and belief, MSN Pvt., by itself and/or through its wholly owned subsidiaries, is in the business of, among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey. MSN Pvt.'s website states that "MSN Laboratories is one of the fastest growing research-based pharmaceutical compan[ies] in India" and has "more than 350 customers across 65 countries around the globe [including] the US."[4]

13. Upon information and belief, MSN Pvt. sells, markets, and distributes generic pharmaceutical products through its U.S. affiliated sales and marketing organization and

[3] http://www.msnlabs.com/msnpi.html (last visited Sept. 30, 2019).

[4] Who We Are, http://www.msnlabs.com/whoweare.html (last visited Sept. 30, 2019). MSN's objectives include "[a]ctively fil[ing] DMFs & . . . ANDAs." Our Future, http://www.msnlabs.com/our-future.html (last visited Sept. 30, 2019).

subsidiary, Novadoz Pharmaceuticals, LLC. Upon information and belief, Novadoz Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of New Jersey, having its principal place of business at 20 Duke Road, Suite A, Piscataway, New Jersey 08854. Upon information and belief, Novadoz Pharmaceuticals, LLC is registered as a wholesale drug distributor in the State of New Jersey under registration number 5005442.

14. Upon information and belief, MSN Pvt. manufactures generic products that are distributed by Novadoz Pharmaceuticals, LLC throughout the United States, including: Rosuvastatin Tablets (5 mg, 10 mg, 20 mg, and 40 mg), Capecitabine Tablets (150 mg and 500 mg), and Moxifloxacin Hydrochloride Tablets (400 mg). Upon information and belief, MSN Pvt. derives substantial revenue from the sale of such generic pharmaceutical products.

15. Upon information and belief, MSN Life Sciences is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana 500018, India.

16. Upon information and belief, MSN Life Sciences is in the business of among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey. MSN Pvt.'s website states that MSN Life Sciences "was established in 2014 and has filed around 50 drug master filings with the USFDA till date."[5] Upon information and belief, MSN Pvt. is the holder of FDA-approved ANDAs for which MSN Life Sciences is the Drug Master File ("DMF") holder for the active ingredient, including ANDA No. 209357 (Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg) and DMF No.

[5] http://www.msnlabs.com/news.html (last visited Sept. 30, 2019).

33365 (Pregabalin USP). Upon information and belief, MSN derives substantial revenue from the sale of such generic pharmaceutical products.

17. Upon information and belief, MSN Life Sciences is the holder of Drug Master File ("DMF") No. 33317 for Cangrelor Tetra Sodium.

18. Upon information and belief, MSN Pvt., MSN Pharmaceuticals, and MSN Life Sciences operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

19. Upon information and belief, MSN Pvt., MSN Pharmaceuticals, and MSN Life Sciences operate as a single integrated business with respect to the regulatory approval, manufacturing, importation, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District. MSN Pvt.'s website states that it is a "well-integrated [p]harmaceutical company" and takes an "integrated view of structures, competencies, tasks and processes" in the manufacturing, marketing, sale and distribution of its generic pharmaceutical products.[6]

20. Upon information and belief, MSN derives substantial revenue from the sale of generic pharmaceutical products in the United States, including in New Jersey.

21. Upon information and belief, Endo is a company organized and existing under the laws of Ireland, having a principal place of business at First Floor, Minerva House First Floor, Ballsbridge, Dublin 4, Ireland. Upon information and belief, Endo was formed in 2019.

22. Upon information and belief, MSN and Endo have submitted ANDA No. 213703 to the FDA, seeking approval to market cangrelor for injection, 50 mg/vial (the "ANDA Product") prior to the expiration of the patents in suit.

[6] *See* Life at MSN, http://www.msnlabs.com/life-at-msn.html (last visited Sept. 30, 2019).

JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

24. This Court has personal jurisdiction over MSN Pharmaceuticals at least because, upon information and belief: (i) MSN Pharmaceuticals' principal place of business is located in Piscataway, New Jersey, which is in this Court's Newark vicinage; (ii) MSN Pharmaceuticals is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District, and in this Court's Newark vicinage; (iii) MSN Pharmaceuticals, together with its parent MSN Pvt., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey, including in the vicinage of Newark; (iv) MSN Pharmaceuticals, together with MSN Pvt. and MSN Life Sciences, has committed, induced, and/or contributed to acts of patent infringement in New Jersey, including in the vicinage of Newark; (v) MSN Pharmaceuticals have previously submitted to the jurisdiction of this Court and have availed themselves of New Jersey's legal protections in at least three prior litigations and previously consented to personal jurisdiction and venue in this Judicial District.[7]

25. This Court has personal jurisdiction over MSN Pvt. at least because, upon information and belief: (i) MSN Pvt. manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) MSN

[7] *See, e.g.*, *Forest Laboratories, LLC, et al. v. MSN Laboratories Private Limited, et al.*, No. 17-10140 (D.N.J. filed Oct. 30, 2017); *Mitsubishi Tanabe Pharma Corp., et al. v. MSN Laboratories Private Ltd.*, et al., No. 17-5302 (D.N.J. filed Jul. 20, 2017); and *Boehringer Ingelheim Pharms., Inc., et al. v. MSN Laboratories Private Limited, et al.*, No. 17-8399 (D.N.J. filed Oct. 16, 2017).

Pvt., through its U.S. affiliate and subsidiary Novadoz Pharmaceuticals, LLC, which has its principal place of business in Piscataway, New Jersey, is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) MSN Pvt. is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its subsidiary MSN Pharmaceuticals for importation, sale, and/or distribution in the State of New Jersey; (iv) MSN Pvt. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District; (v) MSN Pvt., together with MSN Pharmaceuticals and MSN Life Sciences, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vi) MSN Pvt. has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in at least three prior litigations.[8]

26. This Court has personal jurisdiction over MSN Life Sciences at least because, upon information and belief: (i) MSN Life Sciences, together with MSN Pvt. and MSN Pharmaceuticals, is in the business of, among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey; and (ii) MSN Life Sciences, together with MSN Pvt. and MSN Pharmaceuticals, has committed, induced, or contributed to acts of patent infringement in New Jersey.

27. This Court has personal jurisdiction over Endo at least because, upon information and belief: (i) Endo and MSN are partners with respect to ANDA No. 213703, submitted to FDA for the purpose of obtaining approval to engage in the commercial use, sale, importation, and/or

[8] *Mitsubishi Tanabe Pharma Corp., et al. v. MSN Laboratories Private Ltd., et al.*, No. 17-5302 (D.N.J. filed July 20, 2017); *AstraZeneca AB, et al. v. Citron Pharma LLC, et al.*, No. 15-3383 (D.N.J. filed May 15, 2015); and *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals, LLC, et al.*, No. 15-1585 (D.N.J. filed Mar. 2, 2015).

distribution of the ANDA Product throughout the United States, including in New Jersey, prior to the expiration of the patents in suit; and (ii) Endo and MSN are partners with respect to any commercial use, sale, importation, and/or distribution of the ANDA Product throughout the United States, including in New Jersey, upon any final approval of ANDA No. 213703.

28. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 213703 receives final approval, the ANDA Product will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

29. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

30. Federal venue rules do not restrict the locations in which alien corporations, like MSN Pvt., MSN Life Sciences, and Endo, may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354–61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court.

FACTS AS TO ALL COUNTS

31. Chiesi's Kengreal® is sold and marketed under NDA No. 204958, which was approved by FDA as a New Chemical Entity (NCE) on June 22, 2015.

32. Kengreal® is supplied as single-use 10 mL vial containing 50 mg Kengreal® as a lyophilized powder for reconstitution. Cangrelor, the active ingredient in Kengreal®, is a $P2Y_{12}$ platelet inhibitor indicated as an adjunct to percutaneous myocardial infarction (PCI) for reducing the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients in who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

33. NDA No. 204958 pertains to Kengreal®'s 50 mg/vial presentation.

34. Kengreal®'s recommended dosage is 30 mcg/kg administered through intravenous (IV) bolus prior to percutaneous coronary intervention (PCI) followed immediately by a 4 mcg/kg/min intravenous (IV) infusion for at least 2 hours or the duration of the procedure, whichever is longer. Kengreal®'s prescribing information also recommends that in order to maintain platelet inhibition after discontinuation of Kengreal® infusion, an oral $P2Y_{12}$ platelet inhibitor should be administered.

35. FDA's Orange Book lists eight (8) patents as covering Chiesi's Kengreal®. Pursuant to 21 U.S.C. § 355(b)(1), these eight (8) patents were submitted to FDA with NDA No. 204958. These eight (8) patents were subsequently listed in the Orange Book as covering Kengreal®.

36. MSN and Endo sent a letter addressed to Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. dated August 16, 2019, purportedly pursuant to § 505(j)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding ANDA No. 213703 (the "Notice Letter").

37. The Notice Letter states that ANDA No. 213703 has been submitted under § 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration dates of the patents in suit: the '052 patent, the '687 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent.

38. Upon information and belief, ANDA No. 213703 was submitted under § 505(j)(2) of the FDCA with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '052, '687, '448, '921, '575, '265, and '780 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

39. Upon information and belief, the prescribing information for the ANDA Product will have the same Indications and Usage as Kengreal®.

40. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Dosage and Administration as Kengreal®.

41. Upon information and belief, administration of the ANDA Product, will be used to inhibit platelet aggregation in a patient in need thereof.

42. The ’052 patent, titled “Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events,” was duly and legally issued by the U.S. Patent and Trademark Office on March 25, 2014, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, Jayne Prats, and David J. Schneider. Subsequently, The Medicines Company assigned the ’052 patent to Chiesi Farmaceutici S.p.A.

43. The ’687 patent, titled “Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on March 29, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the ’687 patent to Chiesi Farmaceutici S.p.A.

44. The ’448 patent, titled “Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events” was duly and legally issued by the U.S. Patent and Trademark Office on August 30, 2016, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, and Jayne Prats. Subsequently, The Medicines Company assigned the ’448 patent to Chiesi Farmaceutici S.p.A.

45. The ’921 patent, titled “Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same,” was duly and legally issued by the

U.S. Patent and Trademark Office on September 13, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '921 patent to Chiesi Farmaceutici S.p.A.

46. The '575 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on July 11, 2017, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '575 patent to Chiesi Farmaceutici S.p.A.

47. The '265 patent, titled "Methods of Treating or Preventing Stent Thrombosis," was duly and legally issued by the U.S. Patent and Trademark Office on March 27, 2018, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell and Simona Skerjanec. Subsequently, The Medicines Company assigned the '265 patent to Chiesi Farmaceutici S.p.A.

48. The '780 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on August 7, 2018, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '780 patent to Chiesi Farmaceutici S.p.A.

49. The Notice Letter states that MSN and Endo are partners with respect to ANDA No. 213703 and the ANDA Product.

50. Upon information and belief, MSN and Endo were partners in the submission of ANDA No. 213703 to FDA for the purpose of obtaining approval to engage in the commercial use, sale, importation, and/or distribution of the ANDA Product throughout the United States,

including in New Jersey, prior to the expiration of the patents in suit. Upon information and belief, Endo and MSN are partners with respect to any commercial use, sale, importation, and/or distribution of the ANDA Product throughout the United States, including in New Jersey, upon any final approval by FDA of ANDA No. 213703.

51. But for the expiration of any patent for which certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) has been made, any final approval of ANDA No. 213703 shall be effective no earlier than December 22, 2022. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

52. The Notice Letter states that MSN and Endo did not submit a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for U.S. Patent No. 6,130,208 ("the '208 patent).

53. Upon information and belief, MSN and Endo submitted a paragraph III certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '208 patent.

54. Upon information and belief, MSN and Endo are not seeking final FDA approval of ANDA No. 213703 before the patent expiration for the '208 patent. As indicated in the Orange Book, the patent expiration for the '208 patent is June 29, 2023.

55. As indicated in the Orange Book, the patent expiration for the '780 patent is July 10, 2035; the patent expiration for the '052 patent is May 09, 2033; the patent expiration for the '687 patent is July 10, 2035; the patent expiration for the '448 patent is November 10, 2030; the patent expiration for the '921 patent is July 10, 2035; the patent expiration for the '575 patent is July 10, 2035; and the patent expiration for the '265 patent is May 13, 2029.

FIRST COUNT
MSN and Endo's Infringement of the '052 patent

56. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

57. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

58. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

59. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

60. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the ’052 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the ’052 patent.

61. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a “detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

62. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

63. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

64. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '052 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '052 patent is an act of infringement of the '052 patent.

65. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

66. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '052 patent's claims under 35 U.S.C. § 271.

67. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '052 patent under 35 U.S.C. § 271.

68. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

69. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

SECOND COUNT
MSN and Endo's Infringement of the '687 patent

70. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

71. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

72. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

73. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

74. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '687 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '687 patent.

75. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the

factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

76. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

77. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

78. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '687 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '687 patent is an act of infringement of the '687 patent.

79. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

80. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '687 patent's claims under 35 U.S.C. § 271.

81. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '687 patent under 35 U.S.C. § 271.

82. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

83. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

THIRD COUNT
MSN and Endo's Infringement of the '448 patent

84. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

85. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

86. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

87. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

88. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '448 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '448 patent.

89. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

90. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

91. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

92. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '448 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '448 patent is an act of infringement of the '448 patent.

93. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

94. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '448 patent's claims under 35 U.S.C. § 271.

95. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '448 patent under 35 U.S.C. § 271.

96. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

97. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

FOURTH COUNT
MSN and Endo's Infringement of the '921 patent

98. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

99. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

100. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit.

Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

101. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

102. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '921 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '921 patent.

103. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

104. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

105. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175

Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

106. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '921 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '921 patent is an act of infringement of the '921 patent.

107. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

108. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '921 patent's claims under 35 U.S.C. § 271.

109. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '921 patent under 35 U.S.C. § 271.

110. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

111. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

FIFTH COUNT
MSN and Endo's Infringement of the '575 patent

112. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

113. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

114. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

115. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

116. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '575 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '575 patent.

117. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or

each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

118. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

119. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

120. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '575 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '575 patent is an act of infringement of the '575 patent.

121. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

122. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '575 patent's claims under 35 U.S.C. § 271.

123. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '575 patent under 35 U.S.C. § 271.

124. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

125. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

SIXTH COUNT
MSN and Endo's Infringement of the '265 patent

126. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

127. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

128. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

129. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

130. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '265 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '265 patent.

131. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and

legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

132. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

133. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

134. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '265 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '265 patent is an act of infringement of the '265 patent.

135. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

136. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of

the ANDA Product would infringe, directly and/or indirectly, one or more of the '265 patent's claims under 35 U.S.C. § 271.

137. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '265 patent under 35 U.S.C. § 271.

138. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

139. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
MSN and Endo's Infringement of the '780 patent

140. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

141. Upon information and belief, MSN and Endo prepared ANDA No. 213703.

142. Upon information and belief, MSN and Endo submitted ANDA No. 213703 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit. Upon information and belief, ANDA No. 213703 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

143. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

144. Upon information and belief, MSN and Endo submitted ANDA No. 213703 with a paragraph IV certification to the '780 patent for the purpose of obtaining FDA approval to

engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '780 patent.

145. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

146. Upon information and belief, as of the date of Notice Letter, MSN and Endo were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

147. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), MSN and Endo sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

148. Under 35 U.S.C. § 271(e)(2)(A), MSN and Endo's submission of ANDA No. 213703 with a paragraph IV certification to the '780 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '780 patent is an act of infringement of the '780 patent.

149. Upon information and belief, MSN and Endo will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 213703 ever receives final FDA approval.

150. Upon information and belief, MSN and Endo's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '780 patent's claims under 35 U.S.C. § 271.

151. Upon information and belief, MSN and Endo's commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '780 patent under 35 U.S.C. § 271.

152. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

153. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless MSN and Endo are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment declaring that the '052 patent is valid and enforceable;

(B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '052 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '052 patent;

(C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or

importation into the United States of the ANDA Product before the expiration of the '052 patent (including any regulatory extension), would directly and/or indirectly infringe the '052 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the '052 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '052 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '052 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '052 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '052 patent (including any regulatory extension);

(H) A judgment declaring that the '687 patent is valid and enforceable;

(I) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the ’687 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the ’687 patent;

(J) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the ’687 patent (including any regulatory extension), would directly and/or indirectly infringe the ’687 patent;

(K) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the ’687 patent expires (including any regulatory extension);

(L) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’687 patent (including any regulatory extension);

(M) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the ’687 patent (including any regulatory extension);

(N) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '687 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '687 patent (including any regulatory extension);

(O) A judgment declaring that the '448 patent is valid and enforceable;

(P) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '448 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '448 patent;

(Q) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '448 patent (including any regulatory extension), would directly and/or indirectly infringe the '448 patent;

(R) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the '448 patent expires (including any regulatory extension);

(S) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '448 patent (including any regulatory extension);

(T) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '448 patent (including any regulatory extension);

(U) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '448 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '448 patent (including any regulatory extension);

(V) A judgment declaring that the '921 patent is valid and enforceable;

(W) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '921 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '921 patent;

(X) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '921 patent (including any regulatory extension), would directly and/or indirectly infringe the '921 patent;

(Y) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the '921 patent expires (including any regulatory extension);

(Z) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '921 patent (including any regulatory extension);

(AA) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '921 patent (including any regulatory extension);

(BB) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '921 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '921 patent (including any regulatory extension);

(CC) A judgment declaring that the '575 patent is valid and enforceable;

(DD) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '575 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '575 patent;

(EE) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or

importation into the United States of the ANDA Product before the expiration of the ’575 patent (including any regulatory extension), would directly and/or indirectly infringe the ’575 patent;

(FF) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the ’052 patent expires (including any regulatory extension);

(GG) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’575 patent (including any regulatory extension);

(HH) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the ’575 patent (including any regulatory extension);

(II) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants’ infringement of the ’575 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the ’575 patent (including any regulatory extension);

(JJ) A judgment declaring that the ’265 patent is valid and enforceable;

(KK) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the ’265 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the ’265 patent;

(LL) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the ’265 patent (including any regulatory extension), would directly and/or indirectly infringe the ’265 patent;

(MM) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the ’265 patent expires (including any regulatory extension);

(NN) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’265 patent (including any regulatory extension);

(OO) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the ’265 patent (including any regulatory extension);

(PP) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '265 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '265 patent (including any regulatory extension);

(QQ) A judgment declaring that the '780 patent is valid and enforceable;

(RR) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '780 patent by submitting to FDA ANDA No. 213703 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '780 patent;

(SS) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '780 patent (including any regulatory extension), would directly and/or indirectly infringe the '780 patent;

(TT) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 213703 shall be no earlier than the date on which the '780 patent expires (including any regulatory extension);

(UU) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '780 patent (including any regulatory extension);

(VV) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '780 patent (including any regulatory extension);

(WW) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '780 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 213703, prior to the expiration of the '780 patent (including any regulatory extension);

(XX) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Chiesi its attorneys' fees and costs;

(YY) Such other and further relief as this Court may deem just and proper.

Dated: September 30, 2019

Respectfully submitted,

By: /s/ Charles H. Chevalier

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